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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,540	10/30/2001	Gusui Wu	0173.210US	9183

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EXAMINER	
HELMER, GEORGIA L	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,540	WU ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *27Jun, 11Sept2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restricition/Election & Status of the Claims

1. The Office acknowledges the timely receipt of Applicant's Election, dated 14 June 2004, electing the single nucleic acid SEQ ID NO: 1, without traverse. This restriction is made final.

2. Claims 1-30 are pending and are examined with respect to SEQ ID NO: 1 in the instant action.

Claim Objections

The claims are objected to for containing nonelected subject matter, namely SEQ ID NO: 2, 3, and 4. A proper response to this objection a copy of the claims without the nonelected SEQ ID NOs.

Information Disclosure Statement

3. Applicant's IDSs filed 27 June 2002, and 11 September 2002 are acknowledged and signed copies included herewith.

Claim Rejections - 35 USC § 112-written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the best mode contemplated by the inventor of carrying out his invention manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4 and 6-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to (Claims 1-4 and 6-21) an isolated or recombinant nucleic acid molecule comprising a promoter operably linked to a heterologous polynucleotide , wherein the promoter comprising a nucleotide sequence that is at least about 70% identical to a nucleotide sequence SEQ ID NO: 1, and nucleotide sequence that is at least about 80% or 90% identical to a nucleotide sequence SEQ ID NO: 1, and to the promoter specifically hybridizes to a nucleic acid comprising a nucleotide sequence of SEQ ID NO: 1, or a complement thereof. The claims are also drawn to an isolated or recombinant nucleic acid molecule comprising a promoter operably linked to a heterologous polynucleotide, wherein the promoter comprising a nucleotide sequence that is at least 90% identical to 100 contiguous nucleotides in a nucleotide sequence of SEQ ID NO: 1, and to the promoter comprising at least 20 contiguous nucleotides in the nucleotide sequence of SEQ ID NO: 1, and to the promoter comprising at least 40 contiguous nucleotides in a nucleotide sequence of SEQ ID NO: 1. Claims are also drawn to isolated or recombinant nucleic acid molecule comprising a promoter operably linked to a heterologous polynucleotide, wherein the promoter comprising a nucleotide sequence that is at least 90% identical to 100 contiguous nucleotides in a nucleotide sequence of SEQ ID NO: 1, where the promoter is derived from Strawberry vein banding virus (SVBV), and derived from SVBV strain E3, and where the heterologous polynucleotide encodes a polypeptide, or an antisense RNA, or where the heterologous nucleotide comprises a transcription termination signal, or wherein the nucleic acid is a

plasmid, wherein the plasmid comprises a selectable marker and Agrobacterium border sequences, or where the promoter comprises 2 or more enhancer elements, wherein the promoter is chimeric, where the chimeric promoter comprises a minimal promoter region derived from SVBV, or where the chimeric promoter comprises two or more enhancer elements derived from SVBV, or where the nucleic acid molecule is an expression cassette. Claims (22-27) are also drawn to host cell, a plant cell, or a plant, wherein the plant is a monocot or a dicot, transfected with the nucleic acid molecule which is an expression cassette. The claims (28-30) are further drawn to a method of expressing a heterologous polynucleotide in a plant cell, comprising (i) providing an expression cassette comprising a promoter operably linked to a heterologous polynucleotide, wherein the promoter comprises a nucleotide sequence that is at least 90% identical to 100 contiguous nucleotides in a nucleotide sequence of SEQ ID NO: 1, and (ii) introducing the expression cassette into a plant cell wherein the heterologous polynucleotide is expressed, wherein the plant cell is present within a plant and wherein Agrobacterium is used to introduce the nucleic acid molecule into the cell.

Applicants present a complete promoter sequence as set forth in SEQ ID NO:1 (specification, p. 36, lines 13-15), which is sequences 6816-7291 of the SVBV –E3 genome. Applicants do not describe any polynucleotide promoter sequences that are 90%, 80% or 70% identical to SEQ ID NO: 1. Applicant further do not describe any polynucleotide promoter sequences that are at least 90% identical to 100 contiguous nucleotides in a nucleotide sequence of SEQ ID NO: 1, or to the promoter comprising at least 20 contiguous nucleotides in the nucleotide sequence of SEQ ID NO: 1, and to the

promoter comprising at least 40 contiguous nucleotides in a nucleotide sequence of SEQ ID NO: 1.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants fail to describe a representative number of polynucleotide promoter sequences which are at least 70% or 80% or 90% identical to SEQ ID NO:1. Applicants only describe a single promoter sequence (SEQ ID NO:1). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for SEQ ID NO: 1 promoter activity, it remains unclear what features identify a polynucleotide of SEQ ID NO: 1 other than the SEQ ID NO: itself. Since the genus of promoter sequences of SEQ ID NO: 1 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Sequences that are 90%, or 80% or 70% identical with SEQ ID NO: 1 encompass naturally occurring allelic variants, mutants of SEQ ID NO: 1, as well as

sequences having no promoter activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of polynucleotides encompassed by the percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4 and 6-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a isolated nucleic acid comprising a promoter comprising SEQ ID NO: 1, does not reasonably provide enablement for the broad scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Since claims 1-4 and 6-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, one skilled in the art would not know how to make and use this subject matter commensurate in scope with these claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-15, 21-25, and 27-30 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 01/96584 (priority filing 12 June 2000, US 60/210,917, designating the US).

The instant claims are drawn to (Claims 1-4 and 6-21) an isolated or recombinant nucleic acid comprising a promoter operably linked to a heterologous polynucleotide, wherein the promoter comprises a nucleotide sequence that is at least about 70%, 80% or 90% or 100% identical to a nucleotide sequence SEQ ID NO: 1, and to the promoter specifically hybridizes to a nucleic acid comprising a nucleotide sequence of SEQ ID NO: 1, or a complement thereof. The claims are also drawn to an

isolated or recombinant nucleic acid molecule comprising a promoter operably linked to a heterologous polynucleotide, wherein the promoter comprises a nucleotide sequence that is at least 90% identical to 100 contiguous nucleotides in a nucleotide sequence of SEQ ID NO: 1, and to the promoter comprising at least 20 contiguous nucleotides in the nucleotide sequence of SEQ ID NO: 1, and to the promoter comprising at least 40 contiguous nucleotides in a nucleotide sequence of SEQ ID NO: 1. Claims are also drawn to isolated or recombinant nucleic acid molecule comprising a promoter operably linked to a heterologous polynucleotide, wherein the promoter comprising a nucleotide sequence that is at least 90% identical to 100 contiguous nucleotides in a nucleotide sequence of SEQ ID NO: 1, where the promoter is derived from SVBV, and derived from SVBV strain E3, and where the heterologous polynucleotide encodes a polypeptide, or an antisense RNA, or where the heterologous nucleotide comprises a transcription termination signal, or wherein the nucleic acid is a plasmid, wherein the plasmid comprises a selectable marker and Agrobacterium border sequences, or where the promoter comprises 2 or more enhancer elements, wherein the promoter is chimeric, where the chimeric promoter comprises a minimal promoter region derived from SVBV, or where the chimeric promoter comprises two or more enhancer elements derived from SVBV, or where the nucleic acid molecule is an expression cassette. Claims (22-27) are also drawn to host cell, a plant cell, or a plant, wherein the plant is a monocot or a dicot, transfected with the nucleic acid molecule which is an expression cassette. The claims (28-30) are further drawn to a method of expressing a heterologous polynucleotide in a plant cell, comprising (i) providing an expression

cassette comprising a promoter operably linked to a heterologous polynucleotide, wherein the promoter comprises a nucleotide sequence that is at least 90% identical to 100 contiguous nucleotides in a nucleotide sequence of SEQ ID NO: 1, and (ii) introducing the expression cassette into a plant cell wherein the heterologous polynucleotide is expressed, wherein the plant cell is present within a plant and wherein Agrobacterium is used to introduce the nucleic acid molecule into the cell.

WO 01/96584 (hereafter '584) teaches a promoter 100% identical to SEQ ID NO: 1 [(p. 59, SVBV 1) (see attached sequence research results of 2 August 2004, page 1)]. WO '584 teaches this sequence, 100% identical to SEQ ID NO: 1, operably linked to a heterologous polynucleotide, (p. 28 ¶ 121, and Figure 7). This 100% identical sequence, SVBV 1, is inherently 90%, 80%, and 70% identical to SEQ ID NO: 1 (claims 1, 3-5) because the larger length of sequence identity contains the smaller lengths of sequence identity. The SVBV 1 of '584 would also inherently hybridize to the complement of SEQ ID NO:1 (claim 2), because the complementary sequence is the antisense strand to the SEQ ID NO: 1 sense strain. The natural in vivo process of making the complement of SEQ ID NO: 1 requires hybridization of the SEQ ID NO: 1 with its antisense strand. The WO '584 SVBV 1 sequence which is 100 % identical to SEQ ID NO: 1 also inherently comprises a sequence wherein the promoter is at least 90% identical to 100 contiguous nucleotides of SEQ ID NO: 1, or wherein the promoter comprises at least 20 or 40 contiguous nucleotides of SEQ ID NO: 1 (claims 6-8). The '584 sequence encodes an antisense RNA (¶ 122) (claim 12), or a polypeptide (¶ 118). The marker constructs of '584 include nptII and bar, both of which are polypeptides, as

well as transcription termination signals of the nopaline synthase gene (tNOS), (claims 11, 13). The '584 nucleic acid sequences are present in a plant transformation vector plasmid (¶ 121), described a MBCS, npt-II Binary vector(pNOS/NPT-II/tNOS). The term "binary vector[s]" refers to vectors containing Agrobacterium border sequences and the constructs of Figure 7 show the border sequences with a selectable marker between them (claim 15). The nucleic acids of '584 are present as an expression cassette (¶ 120-121, and Figure 7) (claim 21), which Applicant defines as "sequence capable of affecting expression in a structural gene" and which includes at least promoters and transcription termination sequences (specification, p. 6, lines 16-20). WO "584 also teaches a host cell transfected with this nucleic acid (¶ 086, 132), the host being a plant cell within a plant, the transgenic plant containing this host cell, and the host plant being a dicot (claims 22-25 and 27). WO '584 also teaches a method comprising (i) providing an expression cassette comprising a promoter operably linked to the heterologous polynucleotide where the promoter comprises a nucleotide at least 90% identical to 100 contiguous nucleotides in SEQ ID NO: 1, and (ii) introducing the expression cassette into a plant cell, wherein the heterologous polynucleotide is expressed (claim 28). See ('584 ¶ 134-135), which teaches transforming a plant cell with Agrobacterium rhizogenes, and the plant cell being present within a plant (claims 19-30).

Accordingly, WO 01/96584 anticipates the claimed invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-15, and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/96584 (priority filing 12 June 2000, US 60/210,917, designating the US) as discussed above in the 102(e) rejection for claims 1-15, 21-25, and 27-30, in view of Hiei et. al., (US 5,591,616 issued 7 January 1997).

WO 01/96584 does not teach transgenic monocot plants comprising the claims nucleic acids.

Hiei et. al. teaches transformation of monocot plants to produce transgenic plants (Abstract, and claim 1).

Given the recognition of one of ordinary skill in the art of the value of using the claimed invention in whole plants, especially monocot plants, because of the large number of important crop plants which are monocots, because one of ordinary skill in the art would have been motivated to transform monocot plants from the nucleic acids of the claimed invention. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made.

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

Remarks

11. Claims 1-30 are not allowed, given the prior art of record and given the 112.1 rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Georgia L. Helmer
Patent Examiner
Art Unit 1638
August 23, 2004

AMY J. NELSON, PH.D
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